Amendments to the Claims

This listing of claims will replace all prior versions and listings of claims in the application:

Listing of Claims

1-39 (Canceled)

2 ~~40~~. (Currently amended) A drug delivery system according to claim ~~39~~ ~~44~~, wherein said ~~ester~~ dermal penetration enhancer is one or more esters selected from the group consisting of C_8 to C_{18} alkyl para-aminobenzoate, C_8 to C_{18} alkyl dimethyl-para-aminobenzoate, C_8 to C_{18} alkyl cinnamate, C_8 to C_{18} alkyl methoxycinnamate ~~or~~ and C_8 to C_{18} alkyl salicylate.

41-43 (Canceled)

~~44~~. (Previously presented) A non-occlusive, percutaneous or transdermal drug delivery system which comprises:

(i) a therapeutically effective amount of at least one physiologically active agent or prodrug thereof;

(ii) at least one dermal penetration enhancer, which is present in an amount of from 10 to 10,000 wt % based on the weight of the active agent or prodrug thereof;

(iii) at least one volatile liquid present in an amount to act as a vehicle for the active agent and penetration enhancer;

wherein:

the dermal penetration enhancer (A) is adapted to transport the physiologically active agent across a dermal surface or mucosal membrane of an animal, when the volatile liquid evaporates, to form a reservoir or depot of a mixture comprising the penetration enhancer and the physiologically active agent within said surface or membrane, and (B) is of low toxicity to, and is tolerated by, the dermal surface or mucosal membrane of the animal; and,

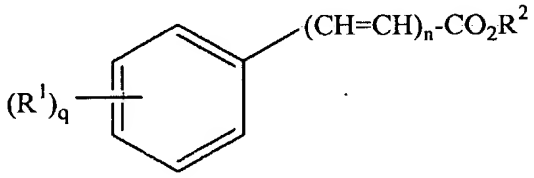
after application of the system to an area of the dermal surface or mucosal membrane, the area becomes touch-dry within 3 minutes of application.

3 ~~45.~~ (Previously presented) A drug delivery system according to claim ~~44~~ 1, wherein the drug delivery system is not supersaturated with respect to the physiologically active agent.

4 ~~46.~~ (Previously presented) A drug delivery system according to claim ~~44~~ 1, wherein the dermal surface or mucosal membrane becomes touch-dry within 1 minute of application.

5 ~~47.~~ (Previously presented) A drug delivery system according to claim ~~44~~ 1, wherein the dermal penetration enhancer is a safe skin tolerant sunscreen.

6 ~~48.~~ (Currently amended) A drug delivery system according to claim ~~44~~ 1, wherein said dermal penetration enhancer is an ester ~~is~~ of formula (I):



(I)

wherein R^1 is hydrogen, lower alkyl, lower alkoxy, halide, hydroxy or NR^3R^4;

R^2 is a long chain alkyl;

R^3 and R^4 are each independently hydrogen, lower alkyl or R^3 and R^4 together with the nitrogen atom to which they are attached form a 5- or 6-membered heterocyclic ring;

n is 0 or 1; and

q is 1 or 2.

7 ~~49.~~ (Currently amended) A drug delivery system according to claim ~~44~~ 1, wherein said ~~ester~~ dermal penetration enhancer is one or more esters selected from the group consisting of a long chain alkyl para-aminobenzoate, long chain alkyl dimethyl-para-aminobenzoate, long chain alkyl cinnamate, long chain alkyl methoxycinnamate ~~or~~ and long chain alkyl salicylate.

8 ~~50.~~ (Currently amended) A drug delivery system according to claim ~~49~~ 7, wherein said dermal penetration enhancer ~~ester~~ is one or more esters selected from the group consisting of octyl dimethyl-para-aminobenzoate, octyl para-methoxycinnamate ~~or~~ and octyl salicylate.

9 ~~51.~~ (Previously presented) A drug delivery system according to claim ~~44,~~ 1 wherein the volatile liquid is ethanol or isopropanol.

10 ~~52.~~ (Currently amended) A drug delivery system according to ~~claim 39 or~~ claim ~~44,~~ 1 wherein the physiologically active agent is a steroid, hormone derivative, non-steroidal anti-inflammatory drug, opioid analgesic, antinauseant, antioestrogen, aromatase inhibitor, 5-alpha reductase inhibitor, anxiolytic, prostaglandin, anti-viral drug, anti-migraine compound, antihypertensive agent, anti-malarial compound, bronchodilator, anti-depressant, anti-Alzheimer's agent, neuroleptic and antipsychotic agent, anti-Parkinson's agent, anti-androgen or anorectic agent.

11 ~~53.~~ (Currently amended) A drug delivery system according to ~~claim 39 or~~ claim ~~44,~~ 1 wherein the physiologically active agent is testosterone, oestradiol, ethinyloestradiol, progesterone, norethisterone acetate, ibuprofen, ketoprofen, flurbiprofen, naproxen, diclofenac, fentanyl, buprenorphine, scopolamine, prochlorperazine, metochlopramide, ondansetron, tamoxifen, epitiostanol, exemestane, 4-hydroxy-androstenedione and its derivatives, finasteride, turosteride, LY191704, MK-306, alprazolam, alprostadil, prostacylcin and its derivatives, melatonin, n-docosanol, tromantadine, lipophilic pro-drugs of acyclovir, low molecular weight heparin, enoxaparin, sumatriptan, amlodipine, nitrendipine, primaquine, minoxidil, minoxidil pro-drugs, pilocarpine, salbutamol, terbutaline, salmeterol, ibogaine, bupropian, rolipram, tacrine, fluphenazine, haloperidol, N-0923, cyproterone acetate or mazindol.

12 ~~54.~~ (Previously presented) A drug delivery system according to claim ~~44,~~ 1 wherein the system is applied to the dermal surface by an aerosol, as a spray.

13 ~~55.~~ (Previously presented) A drug delivery system according to claim ~~54,~~ 12 wherein the aerosol is a fixed or variable metered dose aerosol.

14 ~~56.~~ (Previously presented) A drug delivery system according to claim ~~44,~~ 1 further comprising a pharmaceutical compounding agent, co-solvent, surfactant, emulsifier, antioxidant, preservative, stabiliser, diluent or a mixture of two or more of said components.

15 ~~57.~~ (Currently amended) A method for administering at least one systemic or locally acting physiologically active agent or prodrug thereof to an animal which comprises applying an effective amount of the physiologically active agent in the form of a drug delivery system according to ~~claim 39 or~~ claim ~~44~~ 1 to a dermal surface or mucosal membrane of said animal.

16 ~~58.~~ (Currently amended) A method for the treatment or prophylaxis of a disease or condition in an animal which comprises administering to a dermal surface or mucosal membrane of said animal in need of such treatment a therapeutically effective amount of the drug delivery system according to ~~claim 39 or~~ claim ~~44~~ 1 to a dermal surface or mucosal membrane of said animal.

17 ~~59.~~ (Previously presented) A method according to claim ~~58~~ 16, wherein the disease or condition requires male hormone replacement in testosterone deficient hypogonadal men, female hormone replacement therapy for postmenopausal women, androgen replacement therapy for females lacking libido, male contraception or female contraception.

18 ~~60.~~ (Previously presented) A method according to claim ~~58~~ 16, wherein the disease or condition is soft tissue injury, narcotic withdrawal, severe post-operative pain, motion sickness, oestrogen dependent breast cancer, prostatic enlargement and/or prostatic cancer, alopecia and acne, anxiety disorders, male impotence, Raynaud's syndrome and varicose veins, sleep disorders, jetlag, herpes virus infections, deep vein thrombosis, migraine, high blood pressure, malaria, diagnosis of cystic fibrosis, asthma or nocturnal asthma.

19 ~~61.~~ (Previously presented) A method according to claim ~~57~~ 15, wherein the animal is a human.

62. (Canceled)

20 ~~63.~~ (Previously presented) A transdermal drug delivery system according to claim ~~44~~ 1, wherein the physiologically active agent or prodrug thereof, the dermal penetration enhancer, and the volatile liquid are a single phase.

21 ~~64.~~ (Previously presented) A method according to claim ~~57~~ 15, wherein the drug delivery system is applied by an aerosol or spray comprising a shroud adapted to keep an actuator nozzle of the apparatus at a pre-determined height above the site of application.